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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/434,382	11/05/1999	SEAN V. TAVTIGIAN	2318-247	3879

6449 7590 02/19/2004

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WASHINGTON, DC 20005

EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/434,382	<b>Applicant(s)</b> TAVTIGIAN ET AL.	
	<b>Examiner</b> Anne Holleran	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**P riod for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 11-15, 61-63, 67-77 and 79-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 11-15 and 79 is/are allowed.
- 6) ☒ Claim(s) 61-63, 67-77 and 80-82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

1. The amendment filed 11/03/2003 is acknowledged. Claims 1-3, 61-63, 73-75 were amended. Claims 79-82 were added.
2. Claims 1-3, 11-15, 61-63, 67-77 and 79-82 are pending and examined on the merits.
3. In view of the papers filed 9/6/2002, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the addition of co-inventors Lisa A. Cannon Albright and Susan L. Neuhausen.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

#### ***Claim Rejections Withdrawn:***

4. The rejection of claims 11-13 and 67-75 under 35 U.S.C. 112, first paragraph, because the specification lacks enablement commensurate with the scope of the claims, is withdrawn in view of the amendment to claims 73-75, and upon further consideration of the grounds of rejection with respect to the claimed vectors.

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5. The rejection of claims 1-3 and 61-63 under 35 U.S.C. 102(b) as being anticipated by New England Biolabs (1993/1994 Catalog) is withdrawn in view of the amendment to claims 1-3 and 61-63, and in view of applicants' arguments.

Claims 1-3 and 61-63 are drawn to nucleic acids that are complementary to nucleic acids that encode SEQ ID NO: 1, that comprise SEQ ID NO: 1, SEQ ID NO: 3, or SEQ ID NO: 28. The claims do not recite that the complementary nucleic acids are completely or fully complementary and do not recite size limitations. Therefore, the claims encompass hexamer nucleic acid molecules as described in the New England Biolabs Catalog. Therefore, New England Biolabs teaches nucleic acid molecules that are the same as that claimed.

***New Grounds of Rejection:***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 61-63, 67-77 and 80-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,333,403. Although the conflicting claims are not identical, they are not patentably distinct from each. Claims 61-63 of the instant application are drawn to isolated nucleic acids that contain a base insertion of G between bases that would correspond to codons 547 and 548 of a

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nucleic acid encoding the polypeptide of SEQ ID NO: 2. Thus, the claimed nucleic acids are within the scope of claim 1 of U.S. Patent No. 6,333,403, which is drawn, in part, to an isolated nucleic acid which would encode the polypeptide of SEQ ID NO: 2 but for the presence of a base insertion between what would be codons 547 and 548 of a nucleic acid encoding the polypeptide of SEQ ID NO: 2. In view of the fact that there are only 4 different bases to insert, and in view of the fact that the base insertion of G is the preferred embodiment, the claimed nucleic acids, vectors comprising said nucleic acids, isolated host cells, methods of making polypeptides and cell cultures comprising the isolated host cells, would be obvious to one of ordinary skill in the art over claim 1 of U.S. Patent 6,333,403.

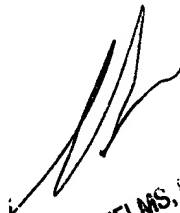
### ***Conclusion***

Claims 1-3, 11, 12-15 and 79 are allowable. Claims 61-63 and 67-77 and 80-82 are rejected.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D. can be reached at (571) 272-0871.

Anne L. Holleran  
Patent Examiner  
February 9, 2004



LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER